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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,392	YU ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,11-14,16,18-20,22,23,25-27 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-7,11-13, 16, 18-20, 22, 23, 25-27, and 38* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments and Remarks filed 4/23/09 in response to the Office Action of 10/23/08 are acknowledged and have been entered.

Claim 38 has been added by Applicant.

Claims 1, 5-7, 11-14, 16, 18-20, 22, 23, 25-27 and 38 are pending.

Claims 1, 5, 11, 12, 14, 16, 22, 27 have been amended by Applicant.

Claims 1, 5-7, 11-14, 16, 18-20, 22, 23, 25-27 and 38 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by amendments.

Objections Withdrawn

The objections to the claims are withdrawn.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn.

The rejection of claims 1 and 11 under 35 U.S.C. 102(b) is withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 16, 18-20, and 22, 23, 25-27 remain rejected and claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Sorlie et al (PNAS, September 2001, 98(19):10869-10874).

Claims 12 and 13 are drawn to an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, and wherein the prognostic set of genes comprises SEQ ID NOs:1-13. It is noted that claims 12 and 13 do not require the apparatus comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the apparatus can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 16 is drawn to a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members. It is noted that claim 16 does not require the kit comprise binding members that specifically bind to any nucleic acids represented

by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 18 is drawn to the kit of claim 16, further comprising a data analysis tool, wherein the data analysis tool is a computer program. Claim 19 is drawn to the kit of claim 18 wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses. Claim 20 is drawn to the kit of claim 16, comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis. Claim 22 is drawn to a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR. It is noted that claim 22 does not require the kit comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 23 is drawn to a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of nucleic acid expression products of a prognostic set of genes wherein the prognostic set

of genes comprises SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample. It is noted that claim 23 does not require identifying expression levels of nucleic acids represented by SEQ ID NOs:1-13; rather, the method requires identifying expression levels of nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 25 is drawn to the method of claim 23 comprising adding the expression profile to a gene expression profile databases. Claim 26 is drawn to the method of claim 23 further comprising comparing the expression profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis. Claim 27 is drawn to the method of claim 26, comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set of genes, and creating a first expression profile from the expression levels of the prognostic set of genes in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of genes of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles. Claim 38 is drawn to the method of claim 27, wherein the known prognosis and known NPI status comprises a known NPI value.

Sorlie et al teaches a method comprising obtaining an expression profile of nucleic acid products of a prognostic set of genes from a patient breast tumor sample, comparing the expression profile with a previously determined standard expression signature profile which is associated with low or high NPI, wherein a prognostic set of nucleic acid products comprises SEQ ID NOs:1-13 (pages 10869-10870, in particular). Sorlie et al teaches said method further comprising classifying the sample of breast tumour, wherein said classifying could be described as being either high NPI or low, or as either of good or bad prognosis NPI relative to a previously determined NPI expression signature profile (Figure 1, in particular). It is noted that Sorlie et al does not use the term NPI; however, the instant claims do not limit as to what is to be required of an NPI expression profile. Sorlie et al further teaches said method further comprising comparing an expression level of a prognostic set in the breast tumour sample before and after treatment (Figure 3, in particular). Sorlie et al further teaches an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said solid support houses nucleic acid binding members for not more than 500 different genes (see Figures 1 and 4, in particular). Sorlie et al further teaches a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit

comprises less than 500 binding members (see Figures 1 and 4, in particular). Sorlie et al further teaches said kit further comprising a data analysis tool, wherein the data analysis tool is a computer program, wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses (left column of page 10870, in particular). Sorlie et al further teaches said kit further comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis (see page 10870, in particular). Sorlie et al further teaches a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes can comprise SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR (see Figures 1 and 4, in particular). Sorlie et al further teaches a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of nucleic acid expression products of a prognostic set of genes wherein the prognostic set of genes can comprise SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample (Figure 1, in particular). Sorlie et al further teaches said method further comprising adding the expression profile to a gene expression profile databases and further comprising comparing the expression profile with a second expression profile or

a plurality of second expression profiles characteristic of a particular prognosis (page 10870 and Figure 3, in particular). Sorlie et al further teaches said method comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set, and creating a first expression profile from the expression levels of the prognostic set in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles (page 10870 and Figure 3, in particular). It is noted that the "known" prognosis, NPI status, and NPI values are inherent properties of a breast tumor sample.

In the Reply of 4/23/09, Applicant argues that Sorlie et al does not suggest a prognostic set of genes comprising SEQ ID NO:1-13.

The amendments to the claims and the arguments found in the Reply of 4/23/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that Sorlie et al does not suggest a prognostic set of genes comprising SEQ ID NO:1-13, the rejected claims do not require presence or use of SEQ ID NOs:1-13. For instance, claims 12 and 13 do not require the apparatus comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the

binding members of the apparatus can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Further, claim 16 does not require the kit comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Further, claim 22 does not require the kit comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Further, claim 23 does not require identifying expression levels of nucleic acids represented by SEQ ID NOs:1-13; rather, the method requires identifying expression levels of nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13.

New Objections

Claim 1 is objected to because of an apparent typographical error. Claim 1 recites: "...either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6 or low NPI (NPI value < the cut-off value of 3.8 to 4.6)...". There appears to be a missing parenthesis bracket. It is noted the following amendment would obviate this objection: "...either high NPI (NPI value at least or greater than a cut-off value of 3.8 to

4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6)...". Proper correction is required.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-7,11-13, 16, 18-20, 22, 23, 25-27, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorlie et al (PNAS, September 2001, 98(19):10869-10874) as applied to claims 12, 13, 16, 18-20, 22, 23, 25-27, and 38

above, and further in view of Sauerbrei et al (Breast Cancer Research and Treatment, 1997, 42: 149-163).

Claim 1 is drawn to a method comprising obtaining an expression profile of nucleic acid products of a prognostic set of genes from a patient breast tumor sample, comparing the expression profile with a previously determined standard expression signature profile which is of known prognoses, wherein the prognostic set of genes comprises SEQ ID NOs:1-13 and assigning the breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6). It is noted that claim 1 does not require the obtained expression profile of nucleic acid products to include any nucleic acids represented by SEQ ID NOs:1-13; rather, the obtained expression profile of nucleic acid products can be any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 5 is drawn to the method of claim 1 comprising the steps of (a) obtaining a breast tumor sample from the patient and (b) measuring the levels of said nucleic acid expression products in the sample. Claim 6 is drawn to the method of claim 5 wherein step (b) comprises contacting said nucleic acid expression products obtained from the sample with a plurality of binding members capable of binding to said nucleic acid expression products, wherein such binding is measured. Claim 7 is drawn to the method of claim 6 wherein the binding members are complementary nucleic acid sequences. Claim 11 is drawn to the method of claim 1 further comprising comparing the expression profiles of the prognostic set of genes in the breast tumour sample before and after treatment. Claims 12 and 13 are drawn to

an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, and wherein the prognostic set of genes comprises SEQ ID NOs:1-13. It is noted that claims 12 and 13 do not require the apparatus comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the apparatus can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 16 is drawn to a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members. It is noted that claim 16 does not require the kit comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 18 is drawn to the kit of claim 16, further comprising a data analysis tool, wherein the data analysis tool is a computer program. Claim 19 is drawn to the kit of claim 18 wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of tumours with differing prognoses. Claim 20 is drawn to the kit of claim 16, comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles

characteristic of a particular prognosis. Claim 22 is drawn to a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR. It is noted that claim 22 does not require the kit comprise binding members that specifically bind to any nucleic acids represented by SEQ ID NOs:1-13; rather, the binding members of the kit can be binding members that bind any nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 23 is drawn to a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of nucleic acid expression products of a prognostic set of genes wherein the prognostic set of genes comprises SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample. It is noted that claim 23 does not require identifying expression levels of nucleic acids represented by SEQ ID NOs:1-13; rather, the method requires identifying expression levels of nucleic acid products which could possibly be part of a prognostic set of genes comprising SEQ ID NOs:1-13. Claim 25 is drawn to the method of claim 23 comprising adding the expression profile to a gene expression profile databases. Claim 26 is drawn to the method of claim 23 further comprising comparing the expression profile with a second expression profile or a

plurality of second expression profiles characteristic of a particular prognosis. Claim 27 is drawn to the method of claim 26, comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of a prognostic set of genes, and creating a first expression profile from the expression levels of the prognostic set of genes in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of genes of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles. Claim 38 is drawn to the method of claim 27, wherein the known prognosis and known NPI status comprises a known NPI value.

Sorlie et al teaches a method comprising obtaining an expression profile of nucleic acid products of a prognostic set of genes from a patient breast tumor sample comprising the steps of (a) obtaining a breast tumor sample from the patient and (b) measuring the levels of nucleic acid expression products in the sample by contacting said nucleic acid expression products obtained from the sample with a plurality of binding members capable of binding to said nucleic acid expression products, wherein such binding is measured; and comparing the expression profile with a previously determined standard expression signature profile which is associated with low or high

NPI, wherein a prognostic set of nucleic acid products comprises SEQ ID NOs:1-13 (pages 10869-10870, in particular). Sorlie et al teaches said method further comprising classifying the sample of breast tumour, wherein said classifying could be described as being either high NPI or low, or as either of good or bad prognosis NPI relative to a previously determined NPI expression signature profile (Figure 1, in particular). It is noted that Sorlie et al does not use the term NPI; however, the instant claims do not limit as to what is to be required of an NPI expression profile. Sorlie et al further teaches said method further comprising comparing an expression level of a prognostic set in the breast tumour sample before and after treatment (Figure 3, in particular). Sorlie et al further teaches an apparatus comprising a solid support to which are attached a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said solid support houses nucleic acid binding members for not more than 500 different genes (see Figures 1 and 4, in particular). Sorlie et al further teaches a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes comprises SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members (see Figures 1 and 4, in particular). Sorlie et al further teaches said kit further comprising a data analysis tool, wherein the data analysis tool is a computer program, wherein the data analysis tool comprises an algorithm adapted to discriminate between the expression profiles of

tumours with differing prognoses (left column of page 10870, in particular). Sorlie et al further teaches said kit further comprising expression profiles from breast tumour samples with known prognoses and/or expression profiles characteristic of a particular prognosis (see page 10870, in particular). Sorlie et al further teaches a kit comprising a plurality of nucleic acid binding members, each binding member being capable of specifically and independently binding to an expression product of one or a prognostic set of genes, wherein the prognostic set of genes can comprise SEQ ID NOs:1-13, and wherein said kit comprises less than 500 binding members, and wherein said binding members are nucleotide primers capable of binding to the nucleic acid expression products of the genes of the prognostic set such that the nucleic acid expression products can be amplified by PCR (see Figures 1 and 4, in particular). Sorlie et al further teaches a method comprising isolated nucleic acid expression products from a breast tumor sample, identifying the expression levels of nucleic acid expression products of a prognostic set of genes wherein the prognostic set of genes can comprise SEQ ID NO:1-13, and producing from the expression levels an expression profile for said breast tumour sample (Figure 1, in particular). Sorlie et al further teaches said method further comprising adding the expression profile to a gene expression profile databases and further comprising comparing the expression profile with a second expression profile or a plurality of second expression profiles characteristic of a particular prognosis (page 10870 and Figure 3, in particular). Sorlie et al further teaches said method comprising the steps (a) isolating nucleic acid expression products from a first breast tumour sample, contacting said expression products with a plurality of

binding members capable of specifically and independently binding to expression products of a prognostic set, and creating a first expression profile from the expression levels of the prognostic set in the tumour sample; (b) isolating nucleic acid expression products from a second breast tumor sample of known prognosis and known NPI status, contacting said expression products with a plurality of binding members capable of specifically and independently binding to expression products of the prognostic set of step (a), so as to create a second expression profile of a breast tumor sample; and (c) comparing the levels of expression products from said first and second expression profiles (page 10870 and Figure 3, in particular). It is noted that the "known" prognosis and NPI status is an inherent property of a breast tumor sample.

Sorlie et al does not specifically teach a method comprising assigning the breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6). However, this deficiency is made up in the teachings of Sauerbrei et al.

Sauerbrei et al teaches a method of determining a prognosis for a patient with breast cancer comprising assigning a breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) (see left column of page 151, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to determine a prognosis for a patient with breast cancer by performing the method of Sorlie et al and assigning breast tumor samples of said method as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low

NPI (NPI value < the cut-off value of 3.8 to 4.6) using the method of Sauerbrei et al because combining two methods of determining a prognosis for breast cancer would be more accurate than performing either method alone. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for determining a prognosis for a patient with breast cancer by performing the method of Sorlie et al and assigning breast tumor samples of said method as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) using the method of Sauerbrei et al because Sauerbrei et al teaches a method of determining a prognosis for a patient with breast cancer comprising assigning a breast tumor sample as being of either high NPI (NPI value at least or greater than a cut-off value of 3.8 to 4.6) or low NPI (NPI value < the cut-off value of 3.8 to 4.6) (see left column of page 151, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Allowable Subject Matter

Claim 14 is allowed.

Summary

Claims 1, 5-7, 11-13, 16, 18-20, 22, 23, 25-27, and 38 are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642